

Applicant(s) : Wen-Tsan Chang et al.
Serial No. : 10/727,355
Filed : December 3, 2003
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Attorney Docket No.: 70001-020001
Client Ref. No.:

REMARKS

This document is submitted in response to the Office Action dated April 18, 2007 ("Office Action"). Claims 1 -30, 32-35, 37-40, and 42 are pending. Claims 1-26, 30, 35, 40, and 42 have been withdrawn and claims 27-29, 32-34, and 37-39 will be under examination. Reconsideration is requested in view of the remarks below.

35 U.S.C. § 102 Rejection

Claims 27-29 and 32-34 remain rejected as anticipated by Morrissey *et al.*, US Patent Application Publication 2003/0206887 ("Morrissey") under § 102(e). See the Office Action, page 2, penultimate paragraph.

With the response to the last office action, Applicants submitted a declaration under 37 CFR 1.131 to show evidence of prior invention. The Examiner countered that "[t]he evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Morrissey *et al.* reference," and that the declaration, as well as the exhibits attached thereto, "fails to satisfactorily establish reduction to practice or conception of the instantly claimed method for reducing and inhibiting viral expression in a cell with the vector comprising SEQ ID NO: 3 prior to the effective date of the reference." See the Office Action, pages 2-3, carryover paragraph and page 4, lines 6-8.

Applicants submit herewith a second declaration under 37 CFR 1.131. As shown in the declaration and Exhibit A attached thereto, Applicants successfully introduced into a cell a vector having SEQ ID NO: 3 and inhibited the expression of an essential HBV protein, HBsAg, prior to the effective date of Morrissey. As described in the specification, HBsAg is required for forming HBV envelope and HBV particles. See, e.g., page 3, lines 20-21. Thus, Applicants did reduce to practice and had conception of the instantly claimed method for reducing and inhibiting viral expression in a cell with a vector comprising SEQ ID NO: 3 prior to the effective date of the Morrissey reference. It is requested that the rejection be withdrawn.

35 U.S.C. § 112 Rejection

Claims 27-29, 32-34, and 37-39 were rejected as being indefinite. See the Office Action, page 6, lines 7-15.

The claims cover methods of inhibiting the replication of a virus in a cell or treating an infection with a virus, using an RNA or a DNA vector containing a nucleic acid encoding the RNA. The RNA includes a first nucleotide sequence, which can be 19-29 nucleotides in length. The Office Action states that “[SEQ ID NO: 3] is the one and only occurrence in which claimed ‘first nucleotide [sequence]’ is described throughout the entire specification... if the recited first nucleotide [sequence] comprises 29 nucleotides in length ..., one skilled in the art would not be able to ascertain the remaining composition/nature of the nucleic acid excluding the target segment sequences (e.g., SEQ ID NO: 3, which is only 19 nucleotides in length).” See the Office Action, page 7, lines 5-8. As such, the Examiner concluded that claims 27-29, 32-34, and 37-39 were indefinite. Applicants respectfully traverse.

First, Applicants disagree that SEQ ID NO: 3 is “the one and only occurrence.” In fact, the specification provides additional exemplary sequences that are longer than 19 nucleotides. See, e.g., page 5, lines 24-25.

Second, as stated in MPEP 2173.02, “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” Further, “[w]hether a claim is invalid for indefiniteness depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the Specification.” *North American Vaccine Inc. v. American Cyanamid Co.*, 28 USPQ2d 1333 (Fed. Cir. 1993).

Here, the specification discloses that the first nucleotide sequence must hybridize under stringent conditions to a segment of a gene. In the case of SEQ ID NO: 3, it must hybridize to the corresponding segment in the gene encoding HBsAg. Accordingly, one possessing the ordinary level of skill in the HBV art would understand that first nucleotide sequence can include SEQ ID NO: 3 and up to 10 additional nucleotides and that the 10 additional nucleotides can be any nucleotides as long as they do not compromise the hybridization of SEQ ID NO: 3 under stringent conditions to the segment. In particular, one possessing the ordinary level of skill in the HBV art could

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recognize that the 10 additional nucleotides can be those in the HBV genome that flank SEQ ID NO: 3. In this connection, Applicants would like to point out that the sequence of the HBV genome and genes therein were well known to one possessing the ordinary level of skill in the pertinent art. See, e.g., Table 1 in Morrissey *et al.*, US Patent Application Publication 2003/0206887, which has been discussed above. In view of the particular application disclosure and the knowledge in art, Applicants submit that those skilled in the art would understand the scope of the claim when the claim is read in light of the Specification. Thus, the claims meet the definiteness requirement and the rejection should be withdrawn.

Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 70001-020001.

Respectfully submitted,

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